

## **REMARKS**

### **Formal Matters**

Claims 128-137 and 145-150 are pending after entry of the amendments set forth herein.

Claims 128-137 and 145-150 were examined. Claims 128-137 and 145-150 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

### **The Office Action**

#### **Claims Rejected Under 35 U.S.C. Section 102(b) (Sears)**

Claims 128-131, 145 and 147-149 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Sears, U.S. Patent No. 3,138,871.

Applicants respectfully traverse.

With regard to claim 128, it is respectfully submitted that Sears does not disclose a device for providing additional stabilization to tissue already in contact with a primary stabilization member. Nor does Sears disclose a tissue contact member, since Sears discloses a spaghetti spoon and a spaghetti spoon does not include a tissue contact member. Nor is the spoon of Sears formed with a loop, but is rather just a convention spoon with a hole positioned through it.

Further claim 128, as amended above recites a lumen in fluid communication with said contact member. It is respectfully submitted that Sears also fails to disclose this feature.

With regard to claim 145, it is respectfully submitted that Sears clearly fails to disclose a device for providing additional stabilization to tissue already in contact with a primary stabilization member. Further, the spoon of Sears does not include at least one tissue contact member adapted to be placed on the tissue in an area bounded by primary tissue contact members.

Further, claim 145 has been amended above to recite that said substantially oval-shaped base member has a second opening through at least a portion thereof, said second opening being located peripherally of said central opening. It is respectfully submitted that Sears fails to disclose such a

second opening.

With regard to claim 147, it is respectfully submitted that Sears fails to disclose a device for providing additional stabilization to tissue already in contact with a primary stabilization member.

It is further respectfully submitted that the spaghetti spoon of Sears lacks at least one tissue contact member adapted to be placed on the tissue in an area bounded by primary tissue contact members.

Further, claim 147 has been amended above to recite a second opening through a portion of said contact member that is not on said bottom surface, said second opening configured to deliver positive pressure therethrough. It is respectfully submitted that the spoon of Sears clearly lacks such a second opening.

With regard to claim 148, it is respectfully submitted that the spaghetti spoon of Sears is not a device for providing additional stabilization to tissue already in contact with a primary stabilization member.

Nor does Sears disclose a substantially rigid, tissue contact member formed in a continuous loop and adapted to be placed on the tissue in an area bounded by primary tissue.

Further, claim 148 has been amended above to recite an opening through a surface of said tissue contact member, said opening in fluid communication with a lumen. It is respectfully submitted that Sears clearly fails to disclose an opening in fluid communication with a lumen as claimed.

Regarding claim 149; it is respectfully submitted that the spaghetti spoon of Sears is not a device for providing additional stabilization to tissue already in contact with a primary stabilization member.

Nor does Sears disclose a single, substantially rigid, tissue contact member formed in a continuous loop and adapted to be placed on the tissue in an area bounded by primary tissue contact members.

Still further, claim 149 has been amended above to recite at least one second opening through said base member; said at least one second opening configured to deliver positive or negative pressure through said base member. It is respectfully submitted that Sears clearly fails to disclose such a second opening.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 128-131, 145 and 147-149 under 35 U.S.C. Section 102(b) as being anticipated by Sears, U.S. Patent No. 3,138,871, as being inappropriate.

**Claims Rejected Under 35 U.S.C. Section 102(b) (Taylor et al.)**

Claims 128-129 and 147-148 were rejected under 35 U.S.C. Section 102(b) as being anticipated by Taylor et al, U.S. Patent No. 6,036,641.

Regarding claims 128, the Examiner asserted that the device of Taylor has a contact surface (area 44) that angles from an exterior portion thereof to an interior portion thereof. The Examiner indicated that either one of the vertical walls of passage 44 is considered to be the exterior portion, and that the bottom surface between the two vertical walls is considered to be the interior portion and that there is an angle or inclination between either one of the vertical walls and the bottom surface therebetween.

Applicants respectfully submit that the only vertical walls of notch 44 are the outer perimeter 1 and the inner annular surface that defines the opening in the center of the device. The notch itself extends from the outer perimeter to the inner perimeter, but is not inclined in the direction from the outer perimeter toward the inner perimeter. The inclined surfaces extend in the circumferential direction of the perimeter. Claim 128 has been amended to clarify that a bottom surface of said contact member includes a contact surface that declines angularly in a radial direction from a periphery of said loop toward an opening in the middle of said loop. It is respectfully submitted that the notch 44 of Taylor et al. is at a constant elevation as it extends in the radial direction from the outer periphery to the inner periphery.

With regard to claim 147, the Examiner asserted that Fig. 8 of Taylor et al. shows an outer perimeter portion 41 that cants upwardly from a lower surface 42. Applicants respectfully traverse. It is respectfully submitted that 42 is a lockable fixture that engages with the distal end of the shaft 43, and is not a lower surface of the base member, but rather an upper surface. However, to further clarify this distinction, Applicants have amended claim 147 to change "lower" to "bottom--".

The Examiner further asserted that the device of Taylor et al. is capable of having the lower surface 42 contacting the tissue while the outer perimeter portion 41, contacts the primary stabilization member. Applicants disagree. Fig. 8 clearly shows that the fixture 42 does not contact tissue, but is on the top side, away from contact. Nor is there any primary stabilization member that the device of Taylor et al. is designed to work with, since the device of Taylor et al. is a primary stabilization device.

Still further, the fixture 42 could not be contacted against the tissue because this would require the shaft 3 to be inserted through the tissue, thereby damaging the tissue.

As to claim 148, the Examiner asserted that Taylor et al. includes a contact surface that angles from an exterior portion (perimeter wall 41) to an interior portion (bottom surface). Applicants

respectfully traverse. It is respectfully submitted that the notch is at the same height where it is formed in the exterior wall as it is where it is formed in the interior wall, and that the entire connecting thickness is also at the same constant height. To further clarify this distinction, claim 148 has been amended to recite that the contact member includes a contact bottom surface that angles from an exterior bottom portion thereof to an interior bottom portion thereof, whereby said interior portion of said contact bottom surface is configured to approximate tissue while allowing said exterior bottom portion to contact upper surfaces of said primary stabilization member. It is respectfully submitted that corresponding portions of the interior portion of the bottom surface of the ring of Taylor et al. are at the same height as those on the exterior portion of the bottom surface. Consequently, the ring of Taylor could not be contacted to upper surfaces of a primary stabilization member while still allowing interior portions of the bottom surface of Taylor et al. to approximate tissue. This is because the primary stabilization member has thickness and the inner and outer portions of the bottom surface of the device of Taylor et al. are at the same height.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 128-129 and 147-148 under 35 U.S.C. Section 102(b) as being anticipated by Taylor et al, U.S. Patent No. 6,036,641, as being inappropriate.

**Claims Rejected Under 35 U.S.C. Section 103(a) (Taylor et al.)**

Claims 130-131, 145 and 149 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Taylor et al., U.S. Patent No. 6,036,641. The Examiner asserted that the device of Taylor et al. has a base member having a contact surface canting upwardly around an outer perimeter thereof. As noted above, Applicants again respectfully submit that 42 is not a contact surface. Further, claim 128, from which claim 130 depends, was amended above to recite that the bottom surface declines angularly in a radial direction from a periphery of said loop toward an opening in the middle of said loop. It is respectfully submitted that Taylor et al. clearly fails to disclose this arrangement. Further, this arrangement serves a distinct function, to allow the outer portion to contact the primary stabilization device while the inner portion can still contact the tissue to be stabilized. Accordingly, it would not have been obvious to modify Taylor to have such a contact surface, since Taylor et al. is a primary stabilization device and needs to apply contact on opposite sides of the target site, therefore teaching away from canting these sides upwardly.

Similarly, with regard to claim 145, the device of Taylor et al. lacks a bottom surface of a contact

member that cants upwardly around an outer perimeter thereof, in a direction from an inner portion of said contact member toward said outer perimeter. Also, Taylor et al teaches away from modify the contact surface so as cant upwardly around the outer perimeter, as this would have a negative effect on the notice 44 that is provided to prevent the contact surface from contacting the coronary artery.

As to claim 149, the device of Taylor et al. lacks a contact bottom surface that cants upwardly in directions from an interior portion thereof to an outer perimeter thereof. Also, Taylor et al teaches away from modify the contact surface so as cant upwardly around the outer perimeter, as this would have a negative effect on the notice 44 that is provided to prevent the contact surface from contacting the coronary artery.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 130-131, 145 and 149 under 35 U.S.C. Section 103(a) as being unpatentable over Taylor et al., U.S. Patent No. 6,036,641, as being clearly inappropriate.

**Claims Rejected Under 35 U.S.C. Section 103(a) (Taylor et al. in view of Borst et al.)**

Claims 132-137, 146 and 150 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Taylor et al., U.S. Patent No. 6,036,641 in view of Borst et al., U.S. Patent No. 5,836,311. The Examiner asserted that Taylor et al. discloses the invention substantially as claimed. For at least the reasons mentioned above under the grounds of rejection of claims 128-129, Applicants respectfully traverse.

It is further noted that, like Taylor et al., Borst et al. also fails to disclose or suggest a device for providing additional stabilization to tissue already in contact with a primary stabilization member and there would therefore have been no motivation to modify Taylor et al. to include a contact surface as claimed.

With regard to claim 146, it is respectfully submitted that neither Taylor et al. nor Borst et al., whether taken separately or in any proper combination, discloses, teaches or suggests at least one tissue contact member adapted to be placed on the tissue in an area bounded by primary tissue contact members, wherein said at least one tissue contact member has a base member having a central opening therethrough, said central opening adapted to allow access to a target site on the tissue, said base member further having a substantially hollow interior adapted to develop a negative pressure therein, wherein said base member further comprises openings through a bottom surface thereof, said openings being fluidly connected with said substantially hollow interior and adapted to apply a negative pressure

to the tissue, and openings through an upper surface thereof, said openings through said upper surface being fluidly connected with a lumen that is connectable with a source of pressure that is independent of a pressure in said substantially hollow interior of said base member, wherein said bottom surface comprises a contact surface that forms at least a part of said bottom surface and inclines upwardly in a direction from an inner portion of said bottom surface towards an outer perimeter of said bottom surface.

With regard to claim 150, it is respectfully submitted that neither Taylor et al. nor Borst et al., whether taken separately or in any proper combination, discloses, teaches or suggests at least one tissue contact member adapted to be placed on the tissue in an area bounded by primary tissue contact members, wherein said at least one tissue contact member comprises a base member having a central opening therethrough, said central opening adapted to allow access to a target site on the tissue, wherein said base member has a substantially hollow interior adapted to develop a negative pressure therein, wherein said base member further comprises openings through a bottom surface thereof, said bottom surface inclined upwardly along a direction from an interior perimeter thereof to an exterior perimeter thereof, said openings being fluidly connected with said substantially hollow interior and adapted to apply a negative pressure to the tissue, and wherein said base member further comprises openings through an upper surface thereof, said openings through said upper surface being fluidly connected with a lumen that is connectable with a source of pressure that is independent of a pressure in said substantially hollow interior of said base member.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 132-137, 146 and 150 under 35 U.S.C. Section 103(a) as being unpatentable over Taylor et al., U.S. Patent No. 6,036,641 in view of Borst et al., U.S. Patent No. 5,836,311, as being clearly inappropriate.

### **Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-021DIV.

Respectfully submitted,  
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Date: March 30, 2009

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